

INFORMATION DISCLOSURE  
CITATION IN AN  
APPLICATION

(PTO-1449)

ATTY. DOCKET NO.  
066872-0039SERIAL NO.  
10/821,669APPLICANT  
ATASSI, M. ZouhairFILING DATE  
April 09, 2004GROUP  
1653 1645

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	Document Number Number-Kind Codes (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
VP 100	1	US 4,551,435	11/05/1985	Liberti et al.	436/541
	2	US 4,643,718	02/17/1987	Marten	604/28
	3	US 6,676,622	01/13/2004	Strahilevitz	604/5.01
	4	US 2004/0175385	09/09/2004	Marks et al.	
	5	US 2002/0155114	10/24/2002	Marks et al.	

## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	Foreign Patent Document Country Codes - Number - Kind Codes (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Figures Appear	Translation	
						Yes	No

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER'S INITIALS	CITE NO.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
VP 100	6	Amersdorfer et al., "Genetic and immunological comparison of anti-botulinum type A antibodies from immune and non-immune human phage libraries," <u>Vaccine</u> 20:1640-1648 (2002).
	7	Amersdorfer et al., "Molecular characterization of murine humoral immune response to botulinum neurotoxin type A binding domain as assessed by using phage antibody libraries," <u>Infect. Immun.</u> 65:3743-3752 (1997).
	8	Aoki, "Pharmacology and immunology of botulinum toxin serotypes," <u>J. Neurol.</u> 248 Suppl. 1:3-10 (2001).
	9	Atassi and Dolimbek, "Mapping of the antibody-binding regions on the HN-domain (residues 449-859) of botulinum neurotoxin A with antitoxin antibodies from four host species. Full profile of the continuous antigenic regions of the H-chain of botulinum neurotoxin A," <u>Protein J.</u> 23:39-52 (2004).
	10	Atassi and Oshima, "Structure, activity, and immune (T and B cell) recognition of botulinum neurotoxins," <u>Crit. Revs. Immunol.</u> 19:219-260 (1999).
	11	Atassi and Smith, "A proposal for the nomenclature of antigenic sites in peptides and proteins," <u>Immunochemistry</u> 15:609-610 (1978).

JPOT 12/9/05

<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>(PTO-1449)</b>	<b>ATTY: DOCKET NO.</b> <b>066872-0039</b>	<b>SERIAL NO.</b> <b>10/821,669</b>
	<b>APPLICANT</b> <b>ATASSI, M. Zouhair</b>	
	<b>FILING DATE</b> <b>April 09, 2004</b>	<b>GROUP</b> <b>1653</b> 1645

12	Atassi et al., "Cross-reaction of mouse antibodies against Tetanus neurotoxin with Botulinum neurotoxins A and B," <i>International Conference 2002, Basic and Therapeutic Aspects of Botulinum and Tetanus Toxins</i> , Hannover, Germany, June 8-12, Abstract R12 (2002).
13	Atassi et al., "Localization and synthesis of the hormone-binding regions of the human thyrotropin receptor," <i>Proc. Natl. Acad. Sci. USA</i> 88:3613-3617 (1991).
14	Atassi et al., "Mapping of the antibody-binding regions on botulinum neurotoxin H-chain domain 855-1296 with anti-toxin antibodies from three host species," <i>J. Prot. Chem.</i> 15:691-700 (1996).
15	Atassi, "Immune recognition and cross-reactivity of botulinum neurotoxins," in <i>Scientific and Therapeutic Aspects of Botulinum Toxins</i> (edited by Brin et al.), pp. 385-408, Lippincott Williams and Wilkins, Philadelphia, PA (2002).
16	Bavari et al., "Identifying the principal protective antigenic determinants of type A botulinum neurotoxin," <i>Vaccine</i> 16:1850-1856 (1998).
17	Cenci Di Bello et al., "Antagonism of the intracellular action of botulinum neurotoxin type A with monoclonal antibodies that map to light-chain epitopes," <i>Eur. J. Biochem.</i> 219:161-169 (1994).
18	Chen et al., "Antibody mapping to domains of botulinum neurotoxin serotype A in the complexed and uncomplexed forms," <i>Infect. Immun.</i> 65:1626-1630 (1997).
19	Clayton and Middlebrook, "Vaccination of mice with DNA encoding a large fragment of botulinum neurotoxin serotype A," <i>Vaccine</i> 18:1855-1862 (2000).
20	Clayton et al., "Protective vaccination with a recombinant fragment of <i>Clostridium botulinum</i> neurotoxin serotype A expressed from a synthetic gene in <i>Escherichia coli</i> ," <i>Infect. Immun.</i> 63:2738-2742 (1995).
21	Dertzbaugh and West, "Mapping of protective and cross-reactive domains of the type A neurotoxin of <i>Clostridium botulinum</i> ," <i>Vaccine</i> 14:1538-1544 (1996).
22	Dolimbek and Atassi, "Protection against alpha-bungarotoxin poisoning by immunization with synthetic toxin peptides," <i>Mol. Immunol.</i> 33:681-689 (1996).
23	Dolimbek et al., "Cross reaction of tetanus and botulinum neurotoxins A and B and the boosting effect of botulinum neurotoxins A and B on a primary anti-tetanus antibody response," <i>Immunological Investigations</i> 31:247-262 (2002).
24	Dressler et al., "Antibody-induced botulinum toxin therapy failure: Can it be overcome by increased botulinum toxin doses?" <i>Eur. Neurol.</i> 47:118-121 (2002).
25	Goschel et al., "Botulinum A toxin therapy: Neutralizing and nonneutralizing antibodies—therapeutic consequences," <i>Exp. Neurol.</i> 147:96-102 (1997).
26	Hambleton et al., "A possible common antigen on clostridial toxins detected by monoclonal anti-botulinum neurotoxin antibodies," 449-450 (1984).
27	Jankovic, "Botulinum Toxin: Clinical Implication of Antigenicity and Immuno-resistance," in Brin et al. eds., <i>Scientific and Therapeutic Aspects of Botulinum Toxin</i> , pp. 409-415, Lippincott Williams & Wilkins, Philadelphia, PA (2002).
28	Klein, "Complications and adverse reactions with the use of botulinum toxin," <i>Dis. Mon.</i> 48:336-356 (2002).

*SPC*



*12/8/05*

<b>INFORMATION DISCLOSURE</b> <b>CITATION IN AN</b> <b>APPLICATION</b>  (PTO-1449)	ATTY. DOCKET NO. <b>066872-0039</b>	SERIAL NO. <b>10/821,669</b>
	APPLICANT <b>ATASSI, M. Zouhair</b>	
	FILING DATE <b>April 09, 2004</b>	GROUP <b>1653 / 1648</b>

29	Kozaki et al., "Development of antitoxin with each of two complementary fragments of <i>Clostridium botulinum</i> type B derivative toxin," <u>Infection and Immunity</u> 18:761-766 (1977).
30	Kozaki et al., "Immunological characterization of Papain-induced fragments of <i>Clostridium botulinum</i> type A neurotoxin and interaction of the fragments with brain synaptosomes," <u>Infection and Immunity</u> 57:2634-2639 (1989).
31	Kozaki et al., "The use of monoclonal antibodies to analyze the structure of <i>Clostridium botulinum</i> type E derivative toxin," <u>Infection and Immunity</u> 52:786-791 (1986).
32	Kubota et al., "Epitope regions in the heavy chain of <i>Clostridium botulinum</i> type E neurotoxin recognized by monoclonal antibodies," <u>Applied &amp; Environmental Microbiol.</u> 63:1214-1218 (1997).
33	Lacy et al., "Crystal structure of botulinum neurotoxin type A and implications for toxicity," <u>Nat. Struct. Biol.</u> 5:898-902 (1998).
34	LaPenotiere et al., "Expression of a large, nontoxic fragment of botulinum neurotoxin serotype A and its use as an immunogen," <u>Toxicon</u> 33:1383-1386 (1995).
35	Middlebrook, "Protection strategies against botulinum toxin," in Atassi and Bixler (Eds.), <u>Immunology of Poreteins and Peptides VIII</u> p. 93-98 Plenum Press New York (1995).
36	Mullaney et al., "Epitope mapping of neutralizing botulinum neurotoxin A antibodies by phage display," <u>Infect. Immun.</u> 69:6511-6514 (2001).
37	Naumann et al., "Depletion of neutralizing antibodies resensitises a secondary non-responder to botulinum A neurotoxin," <u>J. Neurol. Neurosurg. Psychiatry</u> 65:924-927 (1998).
38	Oshima et al., "Antibodies and T cells against synthetic peptides of the C-terminal domain (H <sub>C</sub> ) of botulinum neurotoxin type A and their cross-reaction with H <sub>C</sub> ," <u>Immunol. Letters</u> 60:7-12 (1998).
39	Oshima et al., "Immune recognition of botulinum neurotoxin type A: Regions recognized by T cells and antibodies against the protective H <sub>C</sub> fragment (residues 855-1296) of the toxin," <u>Mol. Immunol.</u> 34:1031-1040 (1997).
40	Pittman et al., "Antibody response to a delayed booster dose of anthrax vaccine and botulinum toxoid," <u>Vaccine</u> 20:2107-2115 (2002).
41	Pless et al., "High-affinity, protective antibodies to the binding domain of botulinum neurotoxin type A," <u>Infect. Immun.</u> 69:570-574 (2001).
42	Rosenberg et al., "Localization of the regions on the C-terminal domain of the heavy chain of botulinum A recognized by T lymphocytes and by antibodies after immunization of mice with pentavalent toxoid," <u>Immunol. Invest.</u> 26:491-504 (1997).
43	Shyu et al., "DNA vaccination using the fragment C of botulinum neurotoxin type A provided protective immunity in mice," <u>J. Biomed. Sci.</u> 7:51-57 (2000).
44	Simeckova-Rosenberg et al., "Protection of mice against lethal viral infection by synthetic peptides corresponding to B- and T-cell recognition sites of influenza A hemagglutinin," <u>Vaccine</u> 13:927-932 (1995).
45	Simpson, "The study of clostridial and related toxins. The search for unique mechanisms and common denominators," <u>J. Physiol., Paris</u> 84:143-151 (1990).
46	Spanoyannis et al., " <i>Clostridium botulinum</i> type B neurotoxin demonstrates cross-reactivity with antibodies from patients with cervical dystonia who no longer respond to type A neurotoxin treatment," <u>Developmental Medicine and Child Neurology</u> 40:33 Scientific poster SP:8 (1998).

*JPant* 12/9/08

<b>INFORMATION DISCLOSURE</b> <b>CITATION IN AN APPLICATION</b>  <b>(PTO-1449)</b>	<b>ATTY. DOCKET NO.</b> <b>066872-0039</b>	<b>SERIAL NO.</b> <b>10/821,669</b>
	<b>APPLICANT</b> <b>ATASSI, M. Zouhair</b>	
	<b>FILING DATE</b> <b>April 09, 2004</b>	<b>GROUP</b> <b>1653 1645</b>

	47	Tsuzuki et al., "Establishment of a monoclonal antibody recognizing an antigenic site common to <i>Clostridium botulinum</i> type B, C <sub>1</sub> , D, and E toxins and tetanus toxin," <u>Infection and Immunity</u> 56:898-902 (1988).	
	48	Wu et al., "Characterization of neutralizing antibodies and identification of neutralizing epitope mimics on the <i>Clostridium botulinum</i> neurotoxin type A," <u>Appl. Environ. Microbiol.</u> 67:3201-3207 (2001).	
<b>EXAMINER</b> 		<b>DATE CONSIDERED</b> <b>12/9/05</b>	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.



**LIST OF REFERENCES CITED BY APPLICANT**

<b>ATTY. DOCKET:</b> 17525(BOT)	<b>SERIAL NO.:</b> 10/821,669
<b>APPLICANT:</b> Atassi	<b>TITLE:</b> BOTULINUM TOXIN A PEPTIDES AND METHODS OF PREDICTING AND REDUCING IMMUNORESISTANCE TO BOTULINUM TOXIN THERAY
<b>FILING DATE:</b> APRIL 9, 2004	<b>GROUP:</b> APPLIED FOR <u>1645</u>

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
<u>VBT</u>	BC	2002/0197278	26 Dec. 2002	Allison			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)

**OTHER REFERENCES**

(Including Author, Title, Date, Pertinent Pages, etc.)

<u>VBT</u>	BD	Singh et al, "Immunochemical characterization of Type A botulinum neurotoxin in its purified and complexed forms.", Toxicon, 1996, Vol. 36, No. 2, pages 267-275
------------	----	--

**EXAMINER** [Signature] **DATE CONSIDERED** 12/8/05

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.